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10/796,171	03/10/2004	Dean E. Cropper	CRP002	3497
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THE HARRIS FIRM			NICHOLSON, KERI JESSICA	
922 N STREET , NW STE . 101				
WASHINGTON, DC 20001			ART UNIT	PAPER NUMBER
			3772	
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			06/25/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/796,171	CROPPER, DEAN E.
	<b>Examiner</b>	<b>Art Unit</b>
	KERI J. NICHOLSON	3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 30 June 2008.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-29 and 32-40 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-29 and 32-40 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

This is the second Office action after the request for reconsideration filed June 1, 2007 for the amendments and arguments files June 30, 2008 based on application 10/796,171. Claims 1-3, 5, 6, 10-12, 15, 17, 19, 20, 23-29, 32, 34, and 36-40 have been amended; claims 1-29 and 32-40 are currently pending.

### ***Specification***

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 1-3, 4, 5, 10-12, 15, 17, 19, 20, 23-29, 32, 34, are 36-40, as currently amended, recited the limitation “a concentrated and active inward tracking member”; however, there is insufficient antecedent basis for the term “active” in the specification.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-3, 4, 5, 10-12, 15, 17, 19, 20, 23-29, 32, 34, are 36-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added term “active” in the limitation “a concentrated and active inward tracking member” is not supported by the original specification such that it is considered new matter. Further, since there is no description

as to what the term “active” is intended to encompass, it has been given the broadest reasonable interpretation as provided by the Merriam-Webster online dictionary, as follows: “marked by present operation, transaction, movement, or use”.

4. Claims 2-14, 16-26, 28, 29, and 33-39 are rejected under 35 U.S.C. 112, first paragraph, for depending from a rejected base claim.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 5-8, 13-17, 19-21, 26-29, 32, 36, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Labour et al. (US Patent 4,445,505).

7. Regarding claim 1, Labour discloses a knee orthosis (10) comprising a medial tracking member (36, 38) that operatively fits along a lateral side of, and provides medial traction to, a patella having a patellafemoral articular tissue and a “concentrated and active” inward elastic tracking member (80) that operatively fits over, and provides inward pressure against, a patella, wherein the inward tracking member (80) is capable of actively providing a concentrated compressive force against the patella when in use thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove.

8. As for claim 2, note that the inward pressure is capable of being applied through an intermittent and progressively increased tightening of the inward tracking member (80).

9. As for claim 3, note that the inward tracking member (80) directly overlays the patella and the medial tracking member so that medial traction can be placed on the patella.

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10. As for claim 5, note that the inward tracking member (80) is adjustable to increase or decrease an amount of inward pressure.

11. As for claim 6, note that the inward tracking member (80) is capable of providing a continuous compressive force against the patella throughout a full range of extension motion of an associated knee.

12. As for claim 7, note that the continuous compressive force can be the same throughout the extension motion.

13. As for claim 8, note that the continuous compressive force increases throughout the extension motion.

14. As for claim 13, note that the members (36, 38) are raised member.

15. As for claim 14, note that the inward tracking member (80) comprises an elastic, adjustable strap.

16. As for claims 15-21, 26, 32, 36, and 37, note the comments relative to the claims above.

17. As for claim 16, note that the inward pressure can be applied through an intermittent and progressively increased tightening of the inward tracking member (80) by adjusting the position of the free end of tracking member (80) relative to member (92) (Fig. 2).

18. As for claim 19, note that the inward tracking member (80) of Labour is capable of being adjusted to increase or decrease an amount of inward pressure.

19. As for claims 20 and 21, note that the inward tracking member is capable of providing continuous compressive force against the patella throughout a full range of extension motion of an associated knee, and wherein the continuous compressive force can be substantially the same throughout the extension motion.

20. As for claim 26, note that the inward tracking member (80) is an elastic strap.

21. As for claims 27-29, note that the device of Labour teaches the recited steps of applying the medial tracking member (36, 38) that operatively fits along a lateral side of, and in doing so providing medial traction to a patella having patellofemoral articular tissue; and applying an inward tracking member (80) that operatively fits over and in doing so would provide inward pressure against, the patella; wherein the inward tracking member (80) would actively provide a compressive force against the patella when in use, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove.

22. As for claim 28, note that if desired by a wearer, when the position of inward tracking member (80) is adjusted, the inward pressure is capable of being applied through an intermittent and progressively increased tightening of the inward tracking member.

23. As for claim 29, note that if desired by a wearer, the medial traction applied through the intermittent and progressively increased tightening of the inward tracking member (80) would increasingly stretch lateral patellar connective tissue over time.

24. As for claims 32, 36, and 37, note the comments relative to the claims above.

25. Claims 1-8, 13- 21, 26- 29, 32-37, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Lehman (US Patent 3,804,084).

26. Regarding claim 1, Lehman teaches a medial tracking member (60, 62) operatively fits along a lateral side of, and capable of providing medial traction to, a patella having patellofemoral articular tissue and a “concentrated and active” inward tracking member (90) that operatively fits over, and capable of providing inward pressure against, the patella; wherein the inward tracking member (90) is capable of actively providing a compressive force against the patella when in use, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove.

27. As for claim 2, note that the inward pressure is capable of being applied through an intermittent and progressively increased tightening of the inward tracking member (90).
28. As for claim 3, note that the inward tracking member (90) directly overlays the patella and the medial tracking member (60, 62) so that medial traction can be placed on the patella.
29. As for claim 4, note that the medial tracking member (60, 62) is adjustable to increase or decrease an amount of medial traction.
30. As for claim 5, note that the inward tracking member (90) is adjustable to increase or decrease an amount of inward pressure.
31. As for claim 6, note that the inward tracking member (90) is capable of providing a continuous compressive force against the patella throughout a full range of extension motion of an associated knee.
32. As for claim 7, note that the continuous compressive force can be the same throughout the extension motion.
33. As for claim 8, note that the continuous compressive force increases throughout the extension motion.
34. As for claim 13, note that the members (60, 62) are raised member.
35. As for claim 14, note that the inward tracking member (90) comprises an elastic, adjustable strap.
36. As for claims 15-21 and 26, note the comments relative to the claims above.
37. As for claim 27, note that the device of Lehman has all structure recited in claim 27 with the medial tracking member (60, 62) and inward tracking member (90) wrapped and secured around the knee in a manner similar to the manner in which Applicant's medial tracking member and Applicant's inward tracking member (90) are wrapped and secured around a knee; wherein in applying the device taught by Lehman to a wearer, one would perform the steps of applying

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the medial tracking member (60, 62) that operatively fits along a lateral side of, and in doing so providing medial traction to, a patella having patellofemoral articular tissue; and applying an inward tracking member (90) that operatively fits over, and in doing so would provide inward pressure against, the patella; wherein the inward tracking member (90) would actively provide a compressive force against the patella when in use, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove.

38. As for claim 28, note that if desired by a wearer, when the position of inward tracking member (90) is adjusted, the inward pressure is capable of being applied through an intermittent and progressively increased tightening of the inward tracking member.

39. As for claim 29, note that if desired by a wearer, the medial traction applied through the intermittent and progressively increased tightening of the inward tracking member (90) would increasingly stretch lateral patellar connective tissue over time.

40. As for claims 32-37, note the medial tracking strap (60, 62), and note the comments relative to the claims above.

41. As for claim 40, note that Lehman teaches the recited steps.

### ***Claim Rejections - 35 USC § 103***

42. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

43. Claims 4, 9-12, 18, 22-25, 33-35, and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Labour et al. (US Patent 4,445,505) in view of Cawley et al. (US Patent 6,551,264) and/or Lehman (US Patent 3,804,084).

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44. Note the comments above for the teaching of Labour et al. Cawley teaches a knee orthosis comprising adjustable medial tracking member (76, 74, 78, 80) (Fig. 1) that operatively fits along a lateral side of, and capable of providing medial traction to a patella having patellofemoral adicular tissue, and teaches the use of polycentric hinge (Fig. 5). Lehman teaches a knee support comprising an adjustable medial tracking member (60, 62) that operatively fits along a lateral side of, and capable of providing medial traction to a patella having patellofemoral adicular tissue. In view of the teachings of Cawley and/or Lehman, it would have been obvious to one ordinary skill in the art at the time the invention was made to modify the device of Labour by providing a polycentric hinge to assist in the motion or bending of the knee, and by providing adjustable medial tracking member in order to adjust the degree of media traction placed on the patella. The provision for a polycentric hinge for a knee brace is well known in the art, and does not provide any unobvious result, and therefore is not patentable over prior art as evidenced by the polycentric hinges taught in US Patents 4,781,179 and 4,572,170.

45. As for claim 4, note that the medial tracking member (76, 74, 78, 80) of Cawley is adjustable to increase or decrease an amount of medial traction.

46. As for claims 9-11 and 22-24, note Figure 5 of Cawley. The provision for a polycentric hinge for a knee brace is well known in the art, and does not provide any unobvious result, and therefore is not patentable over prior art as evidenced by the polycentric hinges taught in US Patents 4,781,179 and 4,572,170.

47. As for claims 12 and 25, note the elastic sleeve (12) of Labour, and note the member (44) of Cawley.

48. As for claims 18, 33-35, 38, and 39, note the comments relative to the claims above.

49. As for claim 40, note that the device of Labour, Cawley, and/or Lehman, in combination, teaches the recited steps.

50. Claims 9-12, 22-25, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehman (US Patent 3,804,084) in view of Cawley et al. (US Patent 6,551,264).

51. Note the comments above for the teaching of Lehman. Cawley teaches a knee orthosis with bicentric hinge (note Fig. 5 of Cawley). In view of this teaching of Cawley, it would have been obvious to one ordinary skill in the art at the time the invention was made to modify the device of Lehman, by providing polycentric hinge to assist in the motion or bending of the knee. The provision for a polycentric hinge for a knee brace is well known in the art, and does not provide any unobvious result, and therefore is not patentable over prior art as evidenced by the polycentric hinges taught in US Patents 4,781,179 and 4,572,170.

52. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Labour et al. (US Patent 4,445,505) in view of Lamping et al. (US Patent 6,485,448).

53. Note the comments above for the teaching of Labour. Lamping teaches rubber tubing (8) covered with elastic material (9) (Fig. 4; column 3, lines 40-54). In view of the teaching of Lamping, it would have been obvious to one ordinary skill in the art at the time the invention was made to provide this structure for the device of Labour to provide more stable or rigid support for the medial tracking member (36, 38).

54. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lehman (US Patent 3,804,084) in view of Lamping et al. (US Patent 6,485,448).

55. Note the comments above for the teaching of Lehman. Lamping teaches rubber tubing (8) covered with elastic material (9) (Fig. 4; column 3, lines 40-54). In view of the teaching of Lamping, it would have been obvious to one ordinary skill in the art at the time the invention was made to provide this structure for the device of Lehman to provide more stable or rigid support for the medial tracking member (60, 62).

### ***Response to Arguments***

56. Applicant's arguments filed June 30, 2008 have been fully considered but they are not persuasive.

57. In response to Applicant's assertion that the support for the limitation "a concentrated and active, inward tracking member" is only found in Figures 1 and 2a-2c, the examiner does not find this persuasive since it remains unclear what Applicant intends to be encompassed by the newly added term "active" and how a figure can define such a term. For examination purposes, the term "active" has only been given the broadest reasonable interpretation as provided by the Merriam-Webster online dictionary as follows: "marked by present operation, transaction, movement, or use". Therefore, the claim has been interpreted such that the inward tracking member merely actively (i.e., operatively) applies a concentrated force or pressure when in use.

58. In response to Applicant's arguments that neither Labour nor Lehman teach "a concentrated and active, inward tracking member", the examiner disagrees. Absent any specific teaching from Applicant's disclosure regarding what is intended by "active" in the specification or claim language, the examiner has given the broadest reasonable interpretation, as explained above, such that the inward tracking member must be capable of actively (i.e., operatively) providing concentrated compression to the patella. In the instant case, both Labour

and Lehman teach inward tracking members which are each capable of actively (i.e., operatively) providing a concentrated force on the patella of a knee when in use. Further, regardless of the whether or not teachings of the term “active” are provided by the specification, it is noted that the features upon which the applicant relies (i.e., what is encompassed by “active”) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Conclusion***

Applicant’s amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KERI J. NICHOLSON whose telephone number is 571-270-3821. The examiner can normally be reached on Monday - Thursday, 8am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KJN  
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6/19/2009

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